

PUMPING FLUID DELIVERY SYSTEMS AND METHODS USING FORCE APPLICATION ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 14/082,579 filed on Nov. 18, 2013, which is a continuation of U.S. patent application Ser. No. 11/704,896 filed on Feb. 9, 2007, which claims the benefit of provisional application 60/772,313, filed Feb. 9, 2006, provisional application 60/789,243, filed Apr. 5, 2006, and provisional application 60/793,188, filed Apr. 19, 2006, each of which is herein incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] This application relates generally to pumping fluid delivery systems and methods using force application assembly.

BACKGROUND

[0003] Many potentially valuable medicines or compounds, including biologicals, are not orally active due to poor absorption, hepatic metabolism or other pharmacokinetic factors. Additionally, some therapeutic compounds, although they can be orally absorbed, are sometimes required to be administered so often it is difficult for a patient to maintain the desired schedule. In these cases, parenteral delivery is often employed or could be employed.

[0004] Effective parenteral routes of drug delivery, as well as other fluids and compounds, such as subcutaneous injection, intramuscular injection, and intravenous (IV) administration include puncture of the skin with a needle or stylet. Insulin is an example of a therapeutic fluid that is self-injected by millions of diabetic patients. Users of parenterally delivered drugs would benefit from a wearable device that would automatically deliver needed drugs/compounds over a period of time.

[0005] To this end, there have been efforts to design portable devices for the controlled release of therapeutics. Such devices are known to have a reservoir such as a cartridge, syringe, or bag, and to be electronically controlled. These devices suffer from a number of drawbacks including the malfunction rate. Reducing the size, weight and cost of these devices is also an ongoing challenge.

SUMMARY OF THE INVENTION

[0006] In one embodiment, the present invention provides a method of dispensing a therapeutic fluid from a line. The method includes providing an inlet line connectable to an upstream fluid source. The inlet line is in downstream fluid communication with a pumping chamber. The pumping chamber has a pump outlet. The method also includes actuating a force application assembly so as to restrict retrograde flow of fluid through the inlet while pressurizing the pumping chamber to urge flow through the pump outlet.

[0007] In a related embodiment, actuating the force application assembly includes using travel of the force application assembly during a work stroke to restrict retrograde flow and to pressurize the pumping chamber in a single mechanical action. In a further related embodiment, a given

degree of travel of the force actuation assembly restricts retrograde flow, and a greater degree of travel pressurizes the pumping chamber.

[0008] In a further related embodiment, actuating the force application assembly includes restricting retrograde flow toward the fluid source by occluding the inlet line. Alternatively or in addition, the method also includes preventing reverse flow of fluid from a dispensing chamber into the pumping chamber by using a passive valve placed therebetween.

[0009] Optionally actuating the force application assembly includes using a shape-memory actuator. Also optionally, using the shape-memory actuator includes inducing a phase change in a shape memory wire to transmit a force around a pulley to the force application assembly.

[0010] In a further embodiment, the method further includes measuring a parameter related to flow through the line; and adjusting operation of the pump based on the measured parameter. Optionally measuring the parameter related to flow through the line includes determining a change in volume of a resilient chamber disposed downstream of the pumping chamber. Optionally, measuring the parameter includes using acoustic volume measurement.

[0011] In a further embodiment, a tortuous flow-impedance located downstream of the resilient chamber supplies a fluid impedance sufficient to cause the resilient chamber to expand in response to pumping.

[0012] Alternatively or in addition, the method further includes causing fluid to flow downstream from the pump outlet through a tortuous flow-impeding conduit. The conduit may have various forms. It may have at least two turns. It may be coiled. It may have a serpentine shape. Optionally, the conduit has a length and an internal diameter selected to provide a predetermined impedance based on at least one of a viscosity and a density of the fluid. Optionally the internal diameter of the conduit is sufficiently large so as to prevent occlusion due to flow of the fluid through the conduit.

[0013] In a further embodiment, the inlet line, the pumping chamber, the pump outlet and the force application assembly are enclosed inside a patch-sized housing, and actuating the force application assembly includes using a processor inside the housing to cause actuation of the force application assembly.

[0014] Optionally, the housing has a largest dimension, and the conduit has a length greater than the largest dimension.

[0015] In a further embodiment, actuating the force application assembly includes inducing using a shape memory actuator. Optionally, using a shape memory actuator includes using one of a plurality of electrical paths of different lengths through the shape-memory actuator, and each electrical path provides a different actuation force.

[0016] In a further embodiment, the force application assembly has a normal mode for normal operation in urging flow through the pump outlet and a priming mode for priming the pumping chamber. In this embodiment, using the shape memory actuator includes using a shorter electrical path of the shape-memory actuator during the normal mode of the force application assembly and using a longer electrical path of the shape-memory actuator during the priming mode of the force application assembly.

[0017] In a further embodiment, the force application assembly operates in at least a basal mode and a bolus mode. When in the basal mode, the pumping chamber outputs fluid